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A simplified method for evaluating swallowing ability and estimating malnutrition risk: A pilot study in older adults --Manuscript Draft--

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Full Title:	A simplified method for evaluating swallowing ability and estimating malnutrition risk: A pilot study in older adults			
Short Title:	Swallowing ability and malnutrition risk			
Corresponding Author:	Orapin Komin, Ph.D. Chulalongkorn University Faculty Of Dentistry Bangkok, Thailand THAILAND			
Keywords:	Nutritional assessment; oral function; Swallowing function; Tongue function; Tongue pressure.			
Abstract:	Objectives: The aim of this pilot study was to develop a Thai-version of a simple swallowing questionnaire, called the T-SSQ, and to evaluate the association between malnutrition risk and swallowing ability, determined objectively by tongue strength and subjectively by the T-SSQ. Sensitivity analysis was also performed to determine which swallowing indices better estimate malnutrition in older adults. Methods: This cross-sectional study comprised two phases: Phase I, development and cross-cultural translation of the T-SSQ; and Phase II, application of the T-SSQ in 60 older adults. In Phase I, content and face validity of the T-SSQ was evaluated by 10 experts and 15 older adults. In Phase II, the convergent validity of the T-SSQ was evaluated by determining its association with objective tongue strength. Nutritional status was evaluated using the Thai-version of the Mini-Nutritional Assessment. Covariates included sociodemographic characteristics, and oral and health-related status. Adjusting for covariates, the associations between the two swallowing indices and malnutrition risk were determined using multivariable regression analyses. A cut-off value for low tongue strength was determined using a receiver operating characteristic (ROC) curve, and sensitivity analysis between the swallowing indices and malnutrition risk was performed. Results: The T-SSQ comprised 4-items of common signs and symptoms of a swallowing problem. Its content and face validity were verified. Older adults were considered as having a swallowing problem when at least one item was reported. Convergent validity of the subjective index was shown by significantly different tongue strength values between the participants with and without a swallowing problem (p for independent t-test = 0.014). Based on the highest area under the ROC curve, an 18-kPa cut-off value was chosen to classify low tongue strength. Having a swallowing problem and low tongue strength was significantly associated with malnutrition risk. The positive predictive value of			
Order of Authors:	Nareudee Limpuangthip			
	Orapin Komin, Ph.D.			
	Teerawut Tatiyapongpaiboon			
Response to Reviewers:	Response to reviewers We are pleased to submit our revised manuscript Number: PONE-D-21-21718. The title has been modified to 'A simplified method for evaluating swallowing ability and estimating malnutrition risk: A pilot study in older adults.' The newly developed questionnaire has been named 'Thai-version of Simplified Swallowing Questionnaire' or 'T-SSQ'. The requested revisions have been made in the manuscript in track			

changes, and our point-by-point responses are below.

Reviewer No. 1:

Reviewer point #1: The authors have embarked on a novel method to identify a screening tool for evaluating swallowing ability in older adults. The manuscript is well written and systematically presented.

However, the conclusions made from this study needs further justification for application on a larger population because its reliability and validity is yet unclear. Probably, this can be introduced as a pilot study to further analyze on the sensitivity of the proposed 4 items self-reported assessment tool.

Author response #1: Thank you for your comment. We have revised our study limitations, further study suggestions and conclusion. Due to a limitation, the study has been changed into a pilot study.

Reviewer point #2: Things that need further clarification include the selection of the items, independence of each item from the other, the scoring value adopted for this tool, the measurement equivalence of the tool, etc.

Author response #2: Development of the T-SSQ including the selection of the items, the scoring value adopted for the T-SSQ, its interpretation, and its validity testing have been clarified in the Materials and Methods section (Phase I subsection, Page 5-6). We did not use any statistical test to evaluate the independence of each item from the other because the items were selected by experts.

Reviewer point #3: The authors do not mention in which language the questionnaire was administered; if in the local language, any translation was done and cross-culturally validated.

Author response #3: Thai language was used for the swallowing questionnaire. The cross-cultural translation from English to Thai version was performed, and the descriptions have been added in the Materials and Methods section (Phase I subsection, Page 5)

Reviewer point #4: The cut off value for the Objective Swallowing Assessment was way below that reported in cited literature and in case that cut-off is raised there is a statistically significant variation between the Objective and Subjective Swallowing tools applied in this study.

Author response #4: The descriptions about the cut-off value have been revised in the Discussion section (Page 15-16) according to the reviewer's suggestion.

Reviewer point #5: The sample size in this study needs to be evaluated if is adequate to introduce a sensitive assessment tool that can be used as a key instrument in early diagnosis and detecting of swallowing impairment among older adults.

Author response #5: The power analysis of the sample size has been revised by evaluating whether the T-SSQ was a sensitive assessment tool for using as a key instrument in early diagnosis and detecting swallowing impairment among older adults. The revisions have been made in the Materials and Methods section (Power analysis subsection, Page 9)

Reviewer No. 2:

Reviewer point #1: Control group should have been included.

Author response #1: Our pilot study did not include patients who were diagnosed with dysphagia by physicians. Therefore, a positive control group was not present in this study. This was because we wanted to develop a screening tool for swallowing ability impairment rather than a tool for dysphagia diagnosis. This limitation has been added in the Discussion section (Page 17).

Reviewer point #2: Newly developed questionnaire should be validated. Statistics data should be furnished completely.

Author response #2: Descriptions about the validation of the newly developed questionnaire (T-SSQ) has been added in the Materials and Methods section (Phase I subsection). The statistical analysis has also been revised.

Reviewer point #3: Relevant figures with legends to be provided. Copy of questionnaire should be given.

Author response #3: The relevant figures with legends have been provided in the manuscript file. A copy of the questionnaire (in Thai, and English translation) has been provided as a supplementary file.

Additional responses to the comments in the attached Pdf files: Materials and Methods section

-The references of the Thai-version of the Mini-Nutritional Assessment (MNA) has

been revised. -The references for the tongue pressure measurement and the Thai-version of Mini-Mental State Evaluation (MMSE) have been added. -To evaluate the reliability of the T-SSQ in older adults, the inter-examiner reliability was examined in 15 patients at the patients' first evaluation visit. Test-retest reliability was evaluated by reinterviewing these patients one week later. The descriptions have been revised in the Swallowing ability assessment subsection (Page 8). Results section -The results for the descriptive statistics have been demonstrated in the Result section and Tables. -The statistical tests have been added as a footnote of Table 1. Discussion section -The patients who were unable to perform a tongue pressure test due to severely declined functional or intellectual conditions were excluded. This exclusion criterion has been included in the Materials and Methods section (Page 5). -The study limitations have been added according to the reviewers' suggestions. Sincerely yours Orapin Komin Corresponding author Additional Information: Question Response Financial Disclosure Yes. This research is funded by Chulalongkorn University, Grant number CU_GR_63_11_32_04. The funders had no role in study design, data collection and Enter a financial disclosure statement that analysis, decision to publish, or preparation of the manuscript. describes the sources of funding for the work included in this submission. Review the submission guidelines for detailed requirements. View published research articles from PLOS ONE for specific examples. This statement is required for submission and will appear in the published article if the submission is accepted. Please make sure it is accurate.

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Title page

A simplified method for evaluating swallowing ability and estimating malnutrition risk: A pilot study in older adults

Short title: Swallowing ability and malnutrition risk

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Abstract

Objectives: The aim of this pilot study was to develop a Thai-version of a simple swallowing questionnaire, called the T-SSQ, and to evaluate the association between malnutrition risk and swallowing ability, determined objectively by tongue strength and subjectively by the T-SSQ. Sensitivity analysis was also performed to determine which swallowing indices better estimate malnutrition in older adults.

Methods: This cross-sectional study comprised two phases: Phase I, development and cross-cultural translation of the T-SSQ; and Phase II, application of the T-SSQ in 60 older adults. In Phase I, content and face validity of the T-SSQ was evaluated by 10 experts and 15 older adults. In Phase II, the convergent validity of the T-SSQ was evaluated by determining its association with objective tongue strength. Nutritional status was evaluated using the Thai-version of the Mini-Nutritional Assessment. Covariates included sociodemographic characteristics, and oral and health-related status. Adjusting for covariates, the associations between the two swallowing indices and malnutrition risk were determined using multivariable regression analyses. A cut-off value for low tongue strength was determined using a receiver operating characteristic (ROC) curve, and sensitivity analysis between the swallowing indices and malnutrition risk was performed.

Results: The T-SSQ comprised 4-items of common signs and symptoms of a swallowing problem. Its content and face validity were verified. Older adults were considered as having a swallowing problem when at least one item was reported. Convergent validity of the subjective index was shown by significantly different tongue strength values between the participants with and without a swallowing problem (p for independent t-test = 0.014). Based on the highest area

under the ROC curve, an 18-kPa cut-off value was chosen to classify low tongue strength.

Having a swallowing problem and low tongue strength was significantly associated with malnutrition risk. The positive predictive value of the subjective swallowing index was 1.8-fold higher than objective tongue strength.

Conclusions: Self-reported swallowing problems determined by the T-SSQ can be used as a subjective index for evaluating swallowing ability in older adults. Subjective swallowing problems and objective tongue strength were associated with malnutrition risk. However, the T-SSQ estimated malnutrition risk better than the objective index.

Keywords: Nutritional assessment, Oral function, Swallowing function, Tongue function, Tongue pressure.

Introduction

Oral and general health functionally decline as people age [1]. Gradually declined oral function can lead to oral frailty followed by oral hypofunction. However, they can recover to the healthy stage by early detection and proper dental treatment [2]. Oral health becomes oral frailty when a person has decreased occluding teeth, increased unchewable foods, or slight choking/spillage while eating. Moreover, oral hypofunction is diagnosed when 3 out of 7 oral signs or symptoms are present: oral uncleanness and dryness, reduced occlusal force, reduced chewing function, reduced tongue and lip motor function, and reduced tongue pressure and swallowing function [2]. Because eating and swallowing ability plays a major role in oral function, a decline in swallowing ability contributes to malnutrition [3, 4]. Malnutrition increases the risk of morbidity and mortality, and negatively affect the quality of life of older adults [5].

To prevent malnutrition in older adults, early detection of declined swallowing ability is necessary. Several objective and subjective indices have been used to evaluate swallowing ability in older adults. Tongue pressure measurement is commonly used to objectively evaluate swallowing ability, because tongue motor function plays an important role in mastication and swallowing [3, 6]. However, this method requires special instruments and time to perform. To evaluate swallowing ability subjectively, the 10-item Eating Assessment Tool (EAT-10) is commonly used because it is considered a reliable and validated questionnaire [2, 6, 7]. However, some studies reported the limitations of EAT-10 regarding its substantial floor effect, several redundant items, and relatively low construct validity [8, 9]. Thus, an alternative simple screening method for evaluating swallowing ability should be proposed for the early detection of oral function when a patient is in the frailty or hypofunction stage.

The aims of the present study were to develop a Thai-version of a simplified swallowing questionnaire (T-SSQ), and to evaluate the association between malnutrition risk and swallowing ability, determined objectively by tongue strength and subjectively by the T-SSQ. In addition, sensitivity analysis was performed to determine which swallowing indices better estimate malnutrition in older adults.

Materials and Methods

Study design and participants

The present study was a cross-sectional design. The study protocol was approved by the Ethics Committee of the Faculty of Dentistry, Chulalongkorn University (HREC-DCU 2018-

112). The participants and their guardians provided written informed consent prior to participating in the study.

The participants were older adults (aged \geq 60 years old) recruited from patients who received dental treatment at the Geriatric and Special Patients Care Clinic, Faculty of Dentistry, Chulalongkorn University during August 2017– January 2019. The exclusion criteria were patients who declined or were unable to perform a tongue pressure test due to severely declined functional or intellectual conditions, or currently had malnutrition.

Phase I. Development of simplified swallowing questionnaire

A 9-item swallowing questionnaire (SQ) was created based on the common signs and symptoms of dysphagia patients according to Walker et al (1990) [10] and Nawaz S & Tulunay-Ugur OE (2018) [11] (Supplementary file 1). Cross-cultural translation of the SQ was performed according to the WHO guidelines [12]. A forward translation from English to the Thai version was conducted by two-independent translators, one dentist and one non-dentist, and integrated into a single Thai version. A back translation from Thai to English version was then conducted by two-independent translators, one was a dentist and the other was not. To verity the content validity of the translated version, the principal investigators and translators discussed any discrepancies related to the meaning of words and phrases between the Thai and English versions. The investigators ensured that the basic concepts and meanings of all terms with reference to the original version were maintained, and then, the Thai-version of the swallowing questionnaire (T-SQ) was proposed.

The content validity of the T-SQ was evaluated by 10 experts (5 physicians and 5 dentists). They gave responses whether they agreed that each of the 9 items indicated a swallowing problem (agree, disagree). The items with less than 80% agreement were excluded, and the final version was reduced to 4 items. A face validity of the 4-item swallowing questionnaire was evaluated in 20 older adults (age range 52–77 years). They gave responses whether they clearly understood the description of each item using a dichotomous scale (clearly understood and unclear), and provided suggestions if any rephrasing was necessary for easier understanding. All items received 90–100% clearly understood response but with some suggestions. After the discrepancies were discussed, a final version of the Thai-version simplified swallowing questionnaire (T-SSQ) was developed. The word liquid in the English version was translated into naam in the Thai version, which means water (noun) or related to liquid substance (adjective) for better understanding by Thais.

The T-SSQ comprised 4 items: 1) having problems swallowing certain food or liquids, or could not swallow at all, 2) coughing or choking when eating or drinking, 3) aspirations with liquids or solid food occurs, and 4) a sensation that food got stuck in the throat or chest. The response to each item was given as having (1) or not having (0) a problem. A person was defined as having a swallowing problem when at least one of items was present at least once a week during the past month.

Phase II. Application of the T-SSQ

Phase II, the T-SSQ application, was conducted as a pilot study in 60 older adults who did not participate in Phase I. Swallowing ability was assessed subjectively by the T-SSQ and objectively by tongue strength. Convergent validity of the T-SSQ was evaluated using objective

tongue pressure as a reference. Sensitivity analysis was performed to determine which subjective and objective swallowing indices better estimate malnutrition in older adults.

Nutritional assessment

Nutritional status was measured using the Thai-version of the Mini-Nutritional Assessment (MNA) with a score ranging from 0–30. The participants were categorized as having malnutrition risk when MNA score = 17–23.5, and being normal when the score ≥24. The MNA was used because it is a standardized and validated instrument in older adults [13, 14].

Swallowing ability assessment

Subjective swallowing ability was evaluated using the T-SSQ developed in Phase I. The participants were interviewed with the assistance of their caregivers, if present. The participants were defined as having a swallowing problem when at least one of the T-SSQ items was reported. The inter-examiner reliability was determined using 15 patients at the patients' first evaluation visit. The test-retest reliability was evaluated by reinterviewing the 15 patients one week later. The weighted Kappa scores for the inter-examiner and test-retest reliability assessments were approximately 0.82 and 0.87, respectively.

The objective swallowing ability was evaluated through tongue pressure, measured using the JMS TPM-02 measurement device (JMS, Inc., Hiroshima, Japan), which consisted of a plastic catheter and a balloon. The participants sat in an upright position. The balloon was inserted into their oral cavity and placed on the anterior part of the palate with their lips and jaw closed, while the plastic catheter was held at the midpoint of the central incisors. The participants raised their tongue and pressed the balloon against the hard palate as hard as possible, and the maximum tongue pressure (kPa, kilopascal) was read. This procedure was done in triplicate with

5 min resting intervals, and the tongue strength (kPa) was calculated from the average value of the three measurements [15-17].

Covariates

Information regarding biological factors, oral- and health-related status was recorded. Biological factors were an individuals' age and sex. A dentist evaluated oral status, comprising the number of remaining functional teeth (ranged from 0 to 28 teeth), number of posterior occluding pairs (ranged 0–8 pairs), and type of denture worn. If more than one type of denture was present, it was classified as the type with the higher number of tooth loss.

Health-related status covered the participants physical and psychological conditions: dependency status and cognitive status, respectively. The clinical frailty scale (CFS) was used to categorize dependency status into independent, semi-dependent, and dependent [18]. Cognitive function was evaluated using the Thai-version of the Mini-Mental State Evaluation (MMSE). With a score ranging from 0–30, the participants were considered as having mild cognitive impairment (MCI) when the score was below 18 and 22 when their educations was at least primary and above primary level, respectively [19].

Power analysis

A power analysis of the sample size was performed to determine whether the T-SSQ was a sensitive assessment tool for using as a key instrument in early diagnosis and detecting swallowing impairment among older adults. The results indicated that the tongue strength (mean \pm s.d.) of the participants who reported a swallowing problem (n₁=7) and those who did not (n₂=54) were 16.8 \pm 10.6 kPa and 26.7 \pm 9.6 kPa, respectively. Using the two-independent means test, a power of 70% was calculated at 5% type I error.

Data analysis

Descriptive statistics was performed to determine the percentage (%) and mean ±standard deviation (s.d.). Univariate analyses of the associations between related variables and having a swallowing problem were analyzed using the chi-squared test, whereas its association with tongue strength and MNA score were analyzed using either one-way ANOVA or independent ttest. Variables with p-value < 0.10 were included in the multivariable analyses. Adjusting for covariates, multivariable logistic and linear regression were used to determine the factors associated with the subjective and objective swallowing indices, and their associations with malnutrition risk. To determine the convergent validity, the tongue strength values of the participants with and without swallowing problem assessed by the T-SSQ were compared using the independent t-test. A receiver operating characteristic (ROC) curve was plotted to determine the area under the curve (AUC) in the malnutrition risk models; the higher the AUC, the better the model was able to distinguish between the participants with and without malnutrition risk. To categorize the low and high tongue strength, a cut-off value that gave the highest AUC value was chosen. For the sensitivity analysis, the positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity between malnutrition risk and the two swallowing ability indices were calculated. The data were analyzed using STATA version 13.0 (StataCorp LP) at a 5% significance level.

Results

The T-SSQ was developed as a subjective swallowing index, comprising 4-items of common signs and symptoms of a swallowing problem. The content and face validity of the T-

SSQ was assessed. The characteristics of the participants attending in Phase II based on the subjective and objective swallowing indices, and malnutrition risk are shown in Table 1. Their mean \pm s.d. age was 78.0 ± 7.0 years old. Malnutrition risk was found in 18% of the participants, while the others were within normal limits. MCI was present in 90% of the semi- and dependent older participants. Oral status was associated with the subjective and objective swallowing indices, and malnutrition risk. The convergent validity of the T-SSQ was revealed as shown by a significant difference in tongue strength values between the participants with and without a swallowing problem (p for independent t-test = 0.014).

Table 1. Characteristics of the study participants.

Variables	Overall	Swallowing abi	Nutritional status	
	distribution:	Self-reported swallowing problem by T-SSQ (Yes):	Maximum tongue pressure (kPa):	MNA score:
	%	%	mean (±s.d.)	mean (±s.d.)
Overall	100.0	11.7	25.5 (±10.1)	26.0 (±3.0)
Age (years): 60 – 69	15.0	11.1	34.5 (±8.7)	25.0 (±3.8)
70 – 79	40.0	4.2	26.8 (±9.3)*	26.5 (±2.1)
80 and above	45.0	18.5^{\dagger}	21.4 (±9.4)*	26.0 (±3.3)
Sex: Male	48.3	10.3	27.7 (±9.8)	26.9 (±2.1)
Female	51.7	12.9	$23.5 \ (\pm 10.1)^{\dagger}$	25.2 (±3.4)
Health-related status				
Dependency status: Independent	71.7	4.6	27.8 (±9.8)	26.9 (±2.1)
Semi-dependent	18.3	27.3*	19.1 (±8.9)*	25.1 (±2.5)
Dependent	10.0	33.3*	21.2 (±8.8)*	21.1 (±3.9)*
MMSE score: Normal	78.3	6.2	26.5 (±10.4)	26.5 (±2.2)
Mild cognitive impairment	21.7	30.8*	$22.1~(\pm 8.6)^{\dagger}$	24.1 (±4.4)
Oral status				
Natural teeth: 0	19.7	16.7	24.1 (±10.2)	$26.0 (\pm 3.6)$
1–19	70.5	11.6	25.2 (±9.7)	25.9 (±3.0)
20 and above	9.8	0.0	30.1 (±9.9)	27.0 (±2.0)
Posterior occluding pairs: 0	76.7	13.0	24.5 (±10.2)	26.1 (±3.0)
1–3	13.3	12.5	32.4 (±10.7)	25.9 (±1.8)
4 and above	10.0	0.0	26.7 (±9.6)	25.4 (±4.5)
Denture type: No denture	3.3	0.0	30.7 (±1.8)	29.2 (±1.1)
Removable partial denture	45.0	7.4	$27.3 (\pm 8.8)$	$26.0 (\pm 2.7)$
Complete denture	51.7	16.1	23.6 (±11.1)	25.8 (±3.2)
Swallowing ability				
Having swallowing problem: No	11.7	-	26.7 (±9.6)	26.0 (±2.8)
Yes	88.3		16.8 (±10.6)*	23.0 (±2.7)*

^{*}p <0.05, †p<0.10 determined by independent t-test or one-way ANOVA and post-hoc comparison test.

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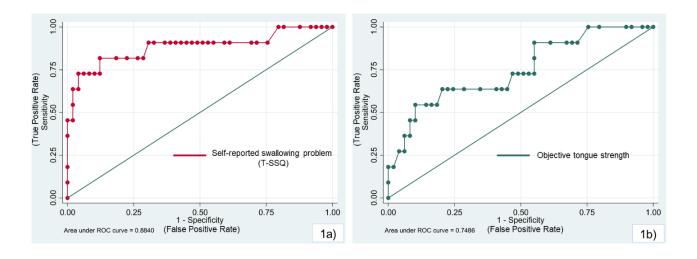
There were significant associations between the subjective and objective swallowing indices and malnutrition risk after adjusting for potential covariates (Table 2). Because there was collinearity between dependency status and MCI, the MCI variable was not included in the multivariable regression models. Based on the ROC curve, 18 kPa was chosen as a cut-off value to categorize the participants into low and high tongue strength because it gave the highest AUC value when plotting the curve between tongue strength and malnutrition risk (Figure 1).

Table 2. The associations between swallowing indices and related variables.

Variables	Swallowing ab	ility index	Malnutrition risk: adjusted OR (95% CI)	
	Self-reported swallowing problem by T-SSQ (Yes):	Maximum tongue pressure (kPa):	Model 1	Model 2
	adjusted OR (95% CI) adjusted β (95% CI)			
Age (years old)	1.05 (0.92, 1.18)	-0.65 (-1.00, -0.30)*	1 (ref)	0.98 (0.84, 1.14)
Sex (Female)	0.55 (0.07, 4.38)	-1.00 (-5.76, 3.76)	6.28 (0.44, 45.4)	3.23 (0.45, 23.4)
Dependency status: Independent	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Semi-dependent	$8.44 (0.89.30.1)^{\dagger}$	-4.19 (-10.6, 2.28)	0.21 (0.01, 6.26)	0.80 (0.07, 8.65)
Dependent	13.4 (1.24, 39.4)*	-6.67 (-14.1, 1.18) [†]	22.3 (1.53, 53.3)*	40.6 (3.30, 85.3)*
Swallowing ability measures				
Self-reported swallowing problem (Yes)			35.5 (3.49, 75.5)*	-
Maximum tongue pressure (<18 kPa)			-	0.11 (0.01, 0.71)*
AUC (%	·)		88.3	74.9

^{*}p <0.05, †p<0.10. OR, odds ratio; β, beta-coefficient; CI, confidence interval; ref, reference; AUC, Area under the Receiver Operating Characteristic (ROC) curve.

Figure 1. Receiver Operating Curves (ROC) and % Area under the ROC curve (AUC) of the association between malnutrition risk and swallowing indices after adjusting for covariates. 1a) Self-reported swallowing problem (T-SSQ), and 1b) Objective tongue strength (18-kPa cut-off value).



Estimates of the PPV, NPV, sensitivity, and specificity are presented in Table 3. The sensitivity value indicated that 45.5% and 36.4% of older adults having malnutrition risk would have a swallowing problem and lower tongue strength, respectively. The PPV values indicated that the participants with a swallowing problem were 1.5–2 folds more likely to have malnutrition risk than those who had lower tongue strength.

Table 3. PPV, NPV, sensitivity, and specificity (%) between swallowing indices and malnutrition risk.

Luncius de sus lleuries e deliter	Malnutrition risk: (%)			
Impaired swallowing ability	PPV	NPV	Sensitivity	Specificity
Self-reported swallowing problem by TSSQ (Yes)	71.4	87.2	45.5	96.0
Low tongue strength: (< 18 kPa)	40.0	86.0	36.4	87.8

Discussion

The present pilot study developed the Thai-version of the simplified swallowing questionnaire (T-SSQ) as a subjective index to evaluate the swallowing ability in older adults. The convergent validity of the T-SSQ was verified using objective tongue pressure as a reference. The findings from this pilot study revealed an association between the subjective and objective swallowing indices and malnutrition risk. Sensitivity analysis demonstrated that the ability of the T-SSQ in estimating malnutrition risk was better than objective tongue strength. In this study, the standard EAT-10 was not used as a subjective swallowing index because some of our patients were unable to understand and complete the EAT-10 questionnaire. Due to its complexity and being time-consuming, our study introduced the T-SSQ for evaluating swallowing ability in older adults. The T-SSQ comprises only 4-item questions with a dichotomous answer, which is simpler than the 10-item questions answered using the 5-point Likert scale in the EAT-10.

Dependent status was significantly associated with low swallowing ability and malnutrition risk. Although the dependency level was associated with advanced age, a higher age was associated with lower tongue strength, but not having a swallowing problem. As supported by previous studies in healthy adults and older people, maximum tongue strength reduced with advanced age [20-22], which might be due to reduced musculoskeletal function [23] and masticatory muscle strength [20]. These findings imply that dependency status has a greater influence on swallowing ability than chronological age. Therefore, maintaining functional health and being active are important to prevent the progression of oral hypofunction in older adults.

The number of remaining teeth, posterior occlusal support, and denture type were not associated with the subjective or objective swallowing indices. Previous studies found that maximum tongue pressure increased with greater posterior occlusal support assessed using the Eicher index [20, 21]. In the present study, however, all edentulous patients wore a dental prosthesis when performing the tongue strength measurement because most of them required anterior denture teeth to position the pressure bulb. Wearing a dental prosthesis increases the number of posterior occlusal contacts, and therefore, enhances the bite force in edentulous individuals [24]. Individuals with higher occlusal forces present higher masticatory muscle strength [20], which is associated with lower dysphagia risk [15, 25]. Thus, wearing a dental prosthesis might reduce malnutrition risk in edentulous older adults regardless of the remaining functional teeth and posterior occlusal support.

In accordance with previous studies in middle-aged and older adults, malnutrition risk was associated with low tongue strength [3, 26]. To categorize low and high tongue strength, our study chose a cut-off value of 18 kPa because it gave the highest AUC value when plotting the ROC curve. The Japanese Society of Gerodontology suggests using 30 kPa as a cut-off value to diagnose decreased tongue strength [2], because a study in Japanese older adults reported that individuals with at least 30-kPa maximum tongue pressure could consume regular food [27]. Furthermore, a study in Canadian older adults in long-term care used a value of 26 kPa, the average tongue pressure of the study samples, as the cut-off value to categorize tongue pressure into low and high levels [3]. In our study, however, using either 30- or 26-kPa tongue pressure as a cut-off value gave relatively low sensitivity and PPV in estimating malnutrition risk, and resulted in a nonsignificant association with a subjective swallowing problem determined by the T-SSQ. However, due to the limited sample size in this pilot study, the 18-cut off value cannot

yet be defined as representative of the Thai population. Because the thickness of the swallowing muscles might be different among ethnicities [28], individual studies may need to identify the ethnic-specific normal values of tongue strength.

The sensitivity of the subjective and objective swallowing indices in estimating malnutrition risk was comparable. However, the PPV value of the T-SSQ was about 1.8-fold greater than that of tongue strength. Moreover, the AUC obtained from the T-SSQ and malnutrition risk was 15.2% higher than the objective tongue strength value. These findings indicated that the T-SSQ might be a more appropriate tool for estimating malnutrition risk in older adults. As supported by earlier studies [11, 29], recognizing signs and symptoms with a thorough history taking is key in early diagnosis and detecting swallowing impairment. Based on our results, we suggest that tongue strength measurement could be a supplemental tool to confirm the subjective finding whenever patients or their caregivers have communication problems or are unaware of the symptoms.

Treating oral frailty and oral hypofunction requires a multidisciplinary approach. Thus, dentists can be part of a holistic team by early detection of declined swallowing function to prevent the progression into the irreversible dysfunction stage [2]. The present study suggests using the T-SSQ as a screening method for evaluating the swallowing ability in older adults that does not require an experienced physician in routine dental practice. In addition, we propose a concept for identifying a cut-off value to categorize lower and higher tongue strength using malnutrition risk as an outcome.

Some limitations were noted in this study. Because all edentulous older adults in this study wore a dental prosthesis and visited the dental clinic for maintenance recall, the swallowing ability of the edentulous patients without a denture or with an ill-fitting denture was

not evaluated. The present pilot study did not include patients who were diagnosed with dysphagia by physicians as a positive control because we wanted to develop a screening tool for swallowing impairment rather than a tool for dysphagia diagnosis. Due to the limited number of samples with 70% study power, the cut-off tongue strength value cannot yet be generalized to other populations. Further study in a larger population is required to verify the reliability, validity, and sensitivity of the questionnaire. Measurement equivalence of the T-SSQ should be performed in older adults with different cultural backgrounds. Convergent validity should be done with other standard subjective swallowing indexes, such as EAT-10 and objective tools, such as video fluoroscopy and fiberoptic endoscopic examination of swallowing [2, 30, 31]. Further use of the simplified questionnaire for early detection of swallowing problem in a clinic and community-based study by caregiver and non-healthcare personnel should be evaluated.

Conclusions

Self-reported swallowing problems determined by the T-SSQ were associated with objective tongue strength, indicating convergent validity of the newly developed subjective index. Both subjective T-SSQ and objective tongue strength indices were associated with malnutrition risk in older adults. However, the subjective T-SSQ better estimated malnutrition risk than the objective tongue strength.

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Conflict of interest

The authors declare no potential conflict of interest and no competing interest in this study

Data availability statement

All relevant data are within the paper and its supporting information files.

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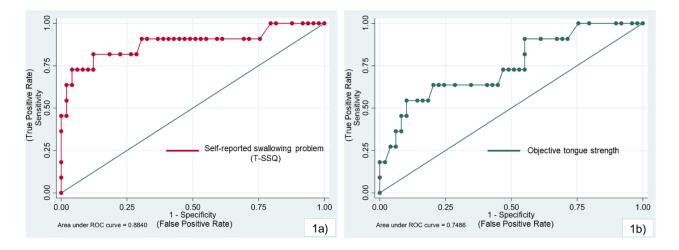
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Figure 1. Receiver Operating Curves (ROC) and % Area under the ROC curve (AUC) of the association between malnutrition risk and swallowing indices after adjusting for covariates. 1a) Self-reported swallowing problem (T-SSQ), and 1b) Objective tongue strength (18-kPa cut-off value).



1b)

Supporting Information1

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Supporting Information

Supplementary File1_Table_swallow.docx

Supporting Information2

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Supporting Information

Supplement File2_Questionnaire Thai_Eng.docx

Raw data

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Title page

1

A simplified method for evaluating swallowing ability and estimating malnutrition risk in older adults: A pilot study in older adults

Short title: Swallowing ability and malnutrition risk

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Abstract

Objectives: The aim of this pilot study was to develop a Thai-version of a simple swallowing questionnaire, called the T-SSQ, and Tto evaluate the association between malnutrition risk and swallowing ability, determined objectively by tongue strength and subjectively by the T-SSQ newly developed 4-item questionnaire. Sensitivity analysis was also performed to determine which swallowing indices better estimate malnutrition in older adults.

Methods: This cross-sectional study comprised two phases: Phase I, development and cross-cultural translation of the T-SSQ; and Phase II, application of the T-SSQ inineluded 60 older adults. In Phase I, content and face validity of the T-SSQ was evaluated by 10 experts and 15 older adults. In Phase II, the convergent validity of the T-SSQ was evaluated by determining its association with objective tongue strength. The dependent variable was nNutritional status was evaluated using the Thai-version of the Mini-Nutritional Assessment. Covariates included sociodemographic characteristics, and oral and health-related status. The independent variables were subjective and objective swallowing ability, evaluated using a 4-item questionnaire of swallowing problems and tongue strength, respectively. Adjusting for covariates, the associations between the two swallowing indices and malnutrition risk were determined using multivariable regression analyses. A cut-off value for low tongue strength was determined using a receiver operating characteristic (ROC) curve, and sensitivity analysis between the swallowing indices and malnutrition risk was performed.

Results: The T-SSQ comprised 4-items of common signs and symptoms of a swallowing problem. Its content and face validity were verified. Older adults were considered as having a swallowing problem when at least one item was reported. Convergent validity of the subjective

index was revealed-shown by significantly different tongue strength values between the participants with and without a swallowing problem (p for independent t-test = 0.014).by its significant association with objective tongue strength. Based on the highest area under the ROC curve, an 18-kPa cut-off value was chosen to classify low tongue strength. Having a swallowing problem and low tongue strength was significantly associated with malnutrition risk. The positive predictive value PPV values of the subjective swallowing index was about 1.8-fold higher than objective tongue strength.

Conclusions: Self-reported swallowing problems <u>determined by the T-SSQ</u> can be used as a subjective index for evaluating swallowing ability in older adults. Subjective swallowing problems and objective tongue strength were associated with malnutrition risk. However, the <u>subjective index-T-SSQ</u> better estimated malnutrition risk <u>better</u> than the objective index.

Keywords: Nutritional assessment, Oral function, Swallowing function, Tongue function, Tongue pressure.

Introduction

Oral and general health functionally decline as people age [1]. Gradually declined oral function can lead to oral frailty followed by oral hypofunction. However, they can recover to the healthy stage by early detection and proper dental treatment_[2]. Oral health becomes oral frailty when a person has decrease ludding teeth, increased unchewable foods, or slight choking/spillage while eating. Moreover, oral hypofunction is diagnosed when 3 out of 7 oral signs or symptoms are present: oral uncleanness and dryness, reduced occlusal force, reduced chewing function, reduced tongue and lip motor function, and as well as reduced tongue pressure

and swallowing function [2]. Because eating and swallowing ability plays a major role in oral function, a decline in swallowing ability contributes to malnutrition [3, 4]. Malnutrition increases the risk of morbidity and mortality, and negatively affect the quality of life of older adults [5].

To prevent malnutrition in older adults, early detection of declined swallowing ability is necessary. Several objective and subjective indices have been used to evaluate swallowing ability in older adults. Tongue pressure measurement is commonly used to objectively evaluate swallowing ability, because tongue motor function plays an important role in mastication and swallowing [3, 6]. However, this method requires special instruments and time to perform. To evaluate swallowing ability subjectively, the 10-item Eating Assessment Tool (EAT-10) is commonly used because it is considered a reliable and validated questionnaire [2, 6, 7]. However, some studies reported the limitations of EAT-10 regarding its substantial floor effect, several redundant items, and relatively low construct validity [8, 9]. Thus, an alternative simple screening method for evaluating swallowing ability should be proposed for the early detection of oral function when a patient is in the frailty or hypofunction stage.

The aims of the present study werewas to develop a Thai-version of a simplified swallowing questionnaire (T-SSQ), and to evaluate the association between malnutrition risk and swallowing ability, determined objectively by tongue strength and subjectively by the T-SSQ newly developed 4 item questionnaire. In addition, sensitivity analysis was performed to determine which swallowing indices better estimate malnutrition in older adults.

Materials and Methods

Study design and participants

The present study was a cross-sectional design. The study protocol was approved by the Ethics Committee of the Faculty of Dentistry, Chulalongkorn University (HREC-DCU 2018-112). The participants and their guardians <u>providedgave</u> written informed consent prior to participating in the study.

The participants were older adults (aged \geq 60 years old) recruited from patients who received dental treatment at the Geriatric and Special Patients Care Clinic, Faculty of Dentistry, Chulalongkorn University during August 2017—January 2019. The exclusion criteria were patients who declined or were unable to perform a tongue pressure test due to severely declined functional or intellectual conditions, or currently had malnutrition. Based on these criteria, 61 older adults aged \geq 60 years old participated in the study.

Power analysis of the sample size was calculated based on the null hypothesis of two independent proportions. The results indicated that the prevalence of malnutrition risk in participants who reported swallowing problem ($n_1=7$) and those who did not ($n_2=54$) were 0.71 and 0.11, respectively. Thus, a power of 95.2% was calculated at 5% type I error.

Phase I. Development of simplified swallowing questionnaire

A 9-item swallowing questionnaire (SQ) was created based on the common signs and symptoms of dysphagia patients according to Walker et al (1990) [10] and Nawaz S & Tulunay-Ugur OE (2018) [11] (Supplementary file 1). Cross-cultural translation of the SQ was performed according to the WHO guidelines [12]. A forward translation from English to the Thai version was conducted by two-independent translators, one dentist and one non-dentist, and integrated into a single Thai version. A back translation from Thai to English version was then conducted

by two-independent translators, one was a dentist and the other was not. To verity the content validity of the translated version, the principal investigators and translators discussed any discrepancies related to the meaning of words and phrases between the Thai and English versions. The investigators ensured that the basic concepts and meanings of all terms with reference to the original version were maintained, and then, the Thai-version of the swallowing questionnaire (T-SQ) was proposed.

The content validity of the T-SQ was evaluated by 10 experts (5 physicians and 5 dentists). They gave responses whether they agreed that each of the 9 items indicated a swallowing problem (agree, disagree). The items with less than 80% agreement were excluded, and the final version was reduced to 4 items. A face validity of the 4-item swallowing questionnaire was evaluated in 20 older adults (age range 52–77 years). They gave responses whether they clearly understood the description of each item using a dichotomous scale (clearly understood and unclear), and provided suggestions if any rephrasing was necessary for easier understanding. All items received 90–100% clearly understood response but with some suggestions. After the discrepancies were discussed, a final version of the Thai-version simplified swallowing questionnaire (T-SSQ) was developed. The word liquid in the English version was translated into naam in the Thai version, which means water (noun) or related to liquid substance (adjective) for better understanding by Thais.

The T-SSQ comprised 4 items: 1) having problems swallowing certain food or liquids, or could not swallow at all, 2) coughing or choking when eating or drinking, 3) aspirations with liquids or solid food occurs, and 4) a sensation that food got stuck in the throat or chest. The response to each item was given as having (1) or not having (0) a problem. A person was defined

as having a swallowing problem when at least one of items was present at least once a week during the past month.

Phase II. Application of the T-SSQ

Phase II, the T-SSQ application, was conducted as a pilot study in 60 older adults who did not participate in Phase I. Swallowing ability was assessed subjectively by the T-SSQ and objectively by tongue strength. Convergent validity of the T-SSQ was evaluated using objective tongue pressure as a reference. Sensitivity analysis was performed to determine which subjective and objective swallowing indices better estimate malnutrition in older adults.

Nutritional assessmentDependent variables

Nutritional status was measured using the Thai-version of the Mini-Nutritional Assessment (MNA) with a score ranging from 0–30. The participants were categorized as having malnutrition risk when MNA score = 17-23.5, and being normal when the score ≥ 24 . The MNA was used because it is a standardized and validated instrument in older adults [13, 14].

Independent variables Swallowing ability assessment

In this study, the subjective swallowing index was a 4-item questionnaire, in which the items
were adopted from common signs and symptoms reported by patients with swallowing problems
[11].

Subjective Sswallowing ability was evaluated using the T-SSQ developed in Phase I. The participants were interviewed by interviewing the participants with the assistance of their caregivers, if present. The participants were defined as having a swallowing problem when at least one of the following signs and symptoms was present at least once a week within the past

month: 1) having problems swallowing certain food or liquids, or could not swallow at all, 2) coughing or choking when eating or drinking, 3) aspirations with liquids or solid food occurs, or 4) a sensation that food got stuck in the throat or chest. The participants were defined as having a swallowing problem when at least one of the T-SSQ items was reported. The inter-examiner reliability was determined using 15 patients at the first patients' first evaluation visit. The intra-examiner reliability was evaluated by reinterviewing these 15 patients one week later. The weighted Kappa scores for the inter- and intrainter-examiner and test-retest reliability assessments were approximately 0.82 and 0.87, respectively.

The objective swallowing ability was evaluated through tongue pressure, measured using the JMS TPM-02 measurement device (JMS, Inc., Hiroshima, Japan), which consisted of a plastic catheter and a balloon-[15-17]. The participants sat in an upright position. The balloon was inserted into their oral cavity and placed on the anterior part of the palate with their lips and jaw closed, while the plastic catheter was held at the midpoint of the central incisors. The participants raised their tongue and pressed the balloon against the hard palate as hard as possible, and the maximum tongue pressure (kPa, kilopascal) was read. This procedure was done in triplicate with 5 min resting intervals, and the tongue strength (kPa) was calculated from the average value of the three measurements [15-17]. The objective tongue strength was used as a reference to assess the convergent validity of the proposed subjective swallowing index.

Covariates

Information regarding biological factors, oral- and health-related status was recorded.

Biological factors were an individuals' age and sex. A dental professional dentist evaluated oral status, comprising the number of remaining functional teeth (ranged from 0 to 28 teeth), number

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of posterior occluding pairs (ranged from 0_to-8 pairs), and type of denture worn. If more than one type of denture was presented, it was classified as the type with then higher number of tooth loss.

Health-related status covered the participants physical and psychological conditions: dependency status and cognitive status, respectively. The clinical frailty scale (CFS) was used to categorize dependency status into independent, semi-dependent, and dependent [18]. Cognitive function was evaluated using the Thai-version of the Mini-Mental State Evaluation (MMSE) [19]. With a score ranging from 0–30, the participants were considered as having mild cognitive impairment (MCI) when the score was below 18 and 22 when their educations was at least primary and above primary level, respectively [19].

Power analysis

A power analysis of the sample size was performed to determine whether the T-SSQ was a sensitive assessment tool for using as a key instrument in early diagnosis and detecting swallowing impairment among older adults. The results indicated that the tongue strength (mean \pm s.d.) of the participants who reported a swallowing problem (n₁=7) and those who did not (n₂=54) were 16.8 \pm 10.6 kPa and 26.7 \pm 9.6 kPa, respectively. Using the two-independent means test, a power of 70% was calculated at 5% type I error.

Data analysis

Descriptive statistics was performed to determine the percentage (%) and mean ±standard deviation (s.d.). Univariate analyses of the associations between related variables and having a swallowing problem were analyzed using the chi-squared test, whereas its association with tongue strength and MNA score were analyzed using either one-way ANOVA or independent t-

test. Variables with p-value < 0.10 were included in the multivariable analyses. Adjusting for covariates, multivariable logistic and linear regression were used to determine the factors associated with the subjective and objective swallowing indices, and their associations with malnutrition risk. To determine the convergent validity, the tongue strength values of the participants with and without swallowing problem assessed by the T-SSQ were compared using the independent t-test. A receiver operating characteristic (ROC) curve was plotted to determine the area under the curve (AUC) in the malnutrition risk models; the higher the AUC, the better the model was able to distinguish between the participants with and without malnutrition risk. To categorize the low and high tongue strength, a cut-off value that gave the highest AUC value was chosen. For the sensitivity analysis, the positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity between malnutrition risk and the two swallowing ability indices were calculated. The data were analyzed using STATA version 13.0 (StataCorp LP) at a 5% significance level.

Results

The T-SSQ was developed as a subjective swallowing index, comprising 4-items of common signs and symptoms of a swallowing problem. The content and face validity of the T-SSQ was assessed. The characteristics of the participants attending in Phase II based on the subjective and objective swallowing indices, and malnutrition risk are shown in Table 1. Their mean \pm s.d. age of participants was 78.0 ± 7.0 years old. Malnutrition risk was found in 18% of the participants, while the others were within normal limits. MCI was present in 90% of the semi- and dependent older participants. Oral status was associated with the subjective and

objective swallowing indices, and malnutrition risk. The convergent validity of the $\underline{\text{T-SSQ}}$ subjective swallowing problem-was revealed as shown by a significant difference in tongue strength values between the participants with and without a swallowing problem (p for independent t-test = 0.014), by its significant association with objective tongue strength.

Table 1. Characteristics of the study participants.

Variables	Overall distribution:	Swallowing abil	Nutritional status	
		Self-reported swallowing problem by T-SSO (Yes):	Maximum tongue pressure (kPa): mean (±s.d.)	MNA score: mean (±s.d.)
	%	%		
Overall	100.0	11.7	25.5 (±10.1)	26.0 (±3.0)
Age (years): 60 – 69	15.0	11.1	34.5 (±8.7)	25.0 (±3.8)
70 – 79	40.0	4.2	26.8 (±9.3)*	26.5 (±2.1)
80 and above	45.0	18.5 [†]	21.4 (±9.4)*	26.0 (±3.3)
Sex: Male	48.3	10.3	27.7 (±9.8)	26.9 (±2.1)
Female	51.7	12.9	$23.5 \ (\pm 10.1)^{\dagger}$	25.2 (±3.4)
Health-related status				
Dependency status: Independent Semi-dependent Dependent	71.7 18.3 10.0	4.6 27.3* 33.3*	27.8 (±9.8) 19.1 (±8.9)* 21.2 (±8.8)*	26.9 (±2.1) 25.1 (±2.5) 21.1 (±3.9)*
MMSE score: Normal	78.3	6.2	26.5 (±10.4)	26.5 (±2.2)
Mild cognitive impairment	21.7	30.8*	22.1 (±8.6) [†]	24.1 (±4.4)
Oral status				
Natural teeth: 0 1–19	19.7 70.5	16.7 11.6	24.1 (±10.2) 25.2 (±9.7)	26.0 (±3.6) 25.9 (±3.0)
20 and above	9.8	0.0	30.1 (±9.9)	27.0 (±2.0)
Posterior occluding pairs: 0 1–3	76.7 13.3	13.0 12.5	24.5 (±10.2) 32.4 (±10.7)	26.1 (±3.0) 25.9 (±1.8)
4 and above	10.0	0.0	26.7 (±9.6)	25.4 (±4.5)
Denture type: No denture	3.3	0.0	30.7 (±1.8)	29.2 (±1.1)
Removable partial denture Complete denture	45.0 51.7	7.4 16.1	27.3 (±8.8) 23.6 (±11.1)	26.0 (±2.7) 25.8 (±3.2)
Swallowing ability				
Having swallowing problem: No	11.7	-	26.7 (±9.6)	26.0 (±2.8)
Yes	88.3		16.8 (±10.6)*	23.0 (±2.7)*

*p <0.05, *p<0.10 determined by independent t-test or one-way ANOVA and post-hoc comparison test. N/A, not applicable due to multicollinearity with dependency status.

OR, odds ratio; β, beta-coefficient; CI, confidence interval; ref, reference.

There were significant associations between the subjective and objective swallowing indices and malnutrition risk after adjusting for potential covariates (Table 2). Because there was

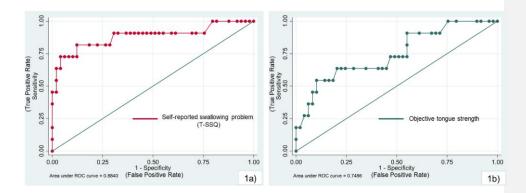
collinearity between dependency status and MCI, the MCI variable was not included in the multivariable regression models. Based on the ROC curve, 18 kPa was chosen as a cut-off value to categorize the participants into low and high tongue strength because it gave the highest AUC value when plotting the curve between tongue strength and malnutrition risk (Figure 1).

Table 2. The associations between swallowing indices and related variables.

Variables	Swallowing ab	ility index	Malnutrition risk: adjusted OR (95% CI)	
	Self-reported swallowing problem by T-SSO (Yes):	Maximum tongue pressure (kPa):	Model 1	Model 2
	adjusted OR (95% CI) adjusted β (95%			
Age (years old)	1.05 (0.92, 1.18)	-0.65 (-1.00, -0.30)*	1 (ref)	0.98 (0.84, 1.14)
Sex (Female)	0.55 (0.07, 4.38)	-1.00 (-5.76, 3.76)	6.28 (0.44, 45.4)	3.23 (0.45, 23.4)
Dependency status: Independent	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Semi-dependent	8.44 (0.89.30.1) [†]	-4.19 (-10.6, 2.28)	0.21 (0.01, 6.26)	0.80 (0.07, 8.65)
Dependent	13.4 (1.24, 39.4)*	-6.67 (-14.1, 1.18) [†]	22.3 (1.53, 53.3)*	40.6 (3.30, 85.3)*
Swallowing ability measures				
Self-reported swallowing problem (Yes)			35.5 (3.49, 75.5)*	-
Maximum tongue pressure (<18 kPa)			-	0.11 (0.01, 0.71)*
AUC (%))		88.3	74.9

*p <0.05, *p<0.10. OR, odds ratio; β, beta-coefficient; CI, confidence interval; ref, reference; AUC, Area under the Receive<u>rd Operating CurveCharacteristic (ROC) curve.</u>

Figure 1. Receiver Operating Curves (ROC) and % Area under the ROC curve (AUC) of the association between malnutrition risk and swallowing indices after adjusting for covariates. 1a) Self-reported_Subjective-swallowing problem (T-SSQ), and 1b) Objective tongue strength (18-kPa cut-off value).



Estimates of the PPV, NPV, sensitivity, and specificity are presented in Table 3. The sensitivity value indicated that 45.5% and 36.4% of older adults having malnutrition risk would have a swallowing problem and lower tongue strength, respectively. The PPV values indicated that the participants with a swallowing problem were 1.5–2 folds more likely to have malnutrition risk than those who had lower tongue strength.

Table 3. PPV, NPV, sensitivity, and specificity (%) between swallowing indices and malnutrition risk.

Impaired swallowing ability	Malnutrition risk: (%)			
impaired swanowing ability	PPV	NPV	Sensitivity	Specificity
Self-reported swallowing problem by TSSQ (Yes)	71.4	87.2	45.5	96.0
Low tongue strength: (< 18 kPa)	40.0	86.0	36.4	87.8

Discussion

The present pilot study developed the Thai-version of the simplified swallowing a 4-item questionnaire (T-SSQ) as a subjective index to evaluate the swallowing ability in older adults. The convergent validity of the subjective swallowing index T-SSQ was verified using objective tongue pressure as a reference. The findings from this pilot study revealed anthe association between the subjective and objective swallowing indices and malnutrition risk. Sensitivity analysis demonstrated that the ability of the T-SSQ subjective swallowing index in estimating malnutrition risk was better than objective tongue strength. In this study, the standard EAT-10 was not used as a subjective swallowing index because some of our patients were unable to understand and complete the EAT-10 questionnaire. Due to its complexity and being time-consuming, our study introduced the T-SSQ a simplified questionnaire for evaluating swallowing ability in older adults. The T-SSQ questionnaire comprises only 4-item questions with a dichotomous answer, which is simpler than the 10-item questions answered using the 5-point Likert scale in the EAT-10.

Dependent status was significantly associated with low swallowing ability and malnutrition risk. Although the dependency level was associated with advanced age, a higher age was associated with lower tongue strength, but not having a swallowing problem. As supported by previous studies in healthy adults and older people, maximum tongue strength reduced with advanced age [20-22], which might be due to reduced musculoskeletal function [23] and masticatory muscle strength [20]. These findings imply that dependency status has a greater influence on swallowing ability than chronological age. Therefore, maintaining functional health and being active are important to prevent the progression of oral hypofunction in older adults.

The number of remaining teeth, posterior occlusal support, and denture type were not associated with the subjective or objective swallowing indices. Previous studies found that maximum tongue pressure increased with greater posterior occlusal support assessed using the Eicher index [20, 21]. In the present study, however, all edentulous patients wore a dental prosthesis when performing the tongue strength measurement because most of them required anterior denture teeth to position the pressure bulb. Wearing a dental prosthesis increases the number of posterior occlusal contacts, and therefore, enhances the bite force in edentulous individuals [24]. Individuals with higher occlusal forces present higher masticatory muscle strength [20], which is associated with lower dysphagia risk [15, 25]. Thus, wearing a dental prosthesis might reduce malnutrition risk in edentulous older adults regardless of the remaining functional teeth and posterior occlusal support.

In accordance with previous studies in middle-aged and older adults, malnutrition risk was associated with low tongue strength [3, 26]. To categorize low and high tongue strength, our study chose a cut-off value of 18 kPa because it gave the highest AUC value when plotting the ROC curve. The Japanese Society of Gerodontology suggests using 30 kPa as a cut-off value to diagnose decreased tongue strength [2]₂- because a study in Japanese older adults reported that individuals with at least 30-kPa maximum tongue pressure could consume regular food [27]. Furthermore, a study in Canadian older adults in long-term care used a value of 26 kPa, the average tongue pressure of the study samples, as the cut-off value to categorize tongue pressure into low and high levels [3]. In our study, however, using either 30- or 26-kPa tongue pressure as a cut-off value gave relatively low sensitivity and PPV in estimating malnutrition risk, and resulted in a nonsignificant association with a subjective swallowing problem determined by the T-SSQ. However, due to the limited sample size in this pilot study, the 18-cut off value cannot

<u>yet be defined as representative of the Thai population.</u> Because the thickness of <u>the</u> swallowing muscles might be different among ethnicities [28], individual studies may need to identify the ethnic-specific normal values of tongue strength.

The sensitivity of the subjective and objective swallowing indices in estimating malnutrition risk was comparable. However, the PPV value of the T-SSQ subjective index was about 1.8-fold greater than that of tongue strength. Moreover, the AUC obtained from the subjective swallowing index T-SSQ and malnutrition risk was 15.2% higher than the objective tongue strength value. These findings indicated that the T-SSQ subjective swallowing index might be a more appropriate tool for estimating malnutrition risk in older adults. As supported by earlier studies [11, 29], recognizing signs and symptoms with a thorough history taking is key in early diagnosis and detecting swallowing impairment. Based on our results, we suggest that T-tongue strength measurement could be a supplemental tool to confirm the subjective finding whenever patients or their caregivers have communication problems or are unaware of the symptoms.

Treating oral frailty and oral hypofunction requires a multidisciplinary approach. Thus, dental professionals dentists can be part of a holistic team by early detection of declined swallowing function to prevent the progression into the irreversible dysfunction stage [2].

This The present study suggests using the T-SSQ a simplified 4 item questionnaire as a screening method for evaluating the swallowing ability in older adults that does not require an experienced physician in routine dental practice. In addition, we propose a concept for identifying a cut-off value to categorize lower and higher tongue strength using malnutrition risk as an outcome.

Some limitations were noted in this study. Because all edentulous older adults in this study wore a dental prosthesis and visited the dental clinic for maintenance recall, the



swallowing ability of the edentulous patients without a denture or with an ill-fitting denture was not evaluated. The present pilot study did not include patients who were diagnosed with dysphagia by physicians as a positive control because we wanted to develop a screening tool for swallowing impairment rather than a tool for dysphagia diagnosis. Due to the limited number of samples with 70% study power, the cut-off tongue strength value cannot yet be generalized to other populations. However, fFurther study in a larger population is required to verify the reliability, and validity, and sensitivity of the questionnaire. Measurement equivalence of the T-SSQ should be performed in older adults with different cultural backgrounds. Convergent validity should be done with other standard subjective swallowing indexes, such as EAT-10 and objective tools, such as video fluoroscopy and fiberoptic endoscopic examination of swallowing [2, 30, 31]. Further use of the simplified questionnaire for early detection of swallowing problem in a clinic and community-based study by caregiver and non-healthcare personnel should be evaluated.

Conclusions

Self-reported swallowing problems determined by the T-SSQ were associated with objective tongue strength, indicating convergent validity of the newly developed subjective index. The 4-item self-reported swallowing problems questionnaire was developed as a subjective index for evaluating swallowing ability in older adults. The convergent validity of the subjective index was verified using objective tongue strength as a reference. Both subjective T-SSQ and objective tongue strength indices were associated with malnutrition risk in older adults. However, the subjective swallowing indexT-SSQ better estimated malnutrition risk than the objective tongue strength.

Acknowledgments

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Conflict of interest

The authors declare no potential conflict of interest and no competing interest in this study

Data availability statement

All relevant data are within the paper and its supporting information files.

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Response to reviewers

We are pleased to submit our revised manuscript Number: PONE-D-21-21718. The title has been modified to 'A simplified method for evaluating swallowing ability and estimating malnutrition risk: A pilot study in older adults.' The newly developed questionnaire has been named 'Thai-version of Simplified Swallowing Questionnaire' or 'T-SSQ'. The requested revisions have been made in the manuscript in track changes, and our point-by-point responses are below.

Reviewer No. 1:

Reviewer point #1: The authors have embarked on a novel method to identify a screening tool for evaluating swallowing ability in older adults. The manuscript is well written and systematically presented.

However, the conclusions made from this study needs further justification for application on a larger population because its reliability and validity is yet unclear. Probably, this can be introduced as a pilot study to further analyze on the sensitivity of the proposed 4 items self-reported assessment tool.

<u>Author response #1</u>: Thank you for your comment. We have revised our study limitations, further study suggestions and conclusion. Due to a limitation, the study has been changed into a pilot study.

Reviewer point #2: Things that need further clarification include the selection of the items, independence of each item from the other, the scoring value adopted for this tool, the measurement equivalence of the tool, etc.

Author response #2: Development of the T-SSQ including the selection of the items, the scoring value adopted for the T-SSQ, its interpretation, and its validity testing have been clarified in the Materials and Methods section (Phase I subsection, Page 5-6). We did not use any statistical test to evaluate the independence of each item from the other because the items were selected by experts.

Reviewer point #3: The authors do not mention in which language the questionnaire was administered; if in the local language, any translation was done and cross-culturally validated.

<u>Author response #3</u>: Thai language was used for the swallowing questionnaire. The cross-cultural translation from English to Thai version was performed, and the descriptions have been added in the Materials and Methods section (Phase I subsection, Page 5)

Reviewer point #4: The cut off value for the Objective Swallowing Assessment was way below that reported in cited literature and in case that cut-off is raised there is a statistically significant variation between the Objective and Subjective Swallowing tools applied in this study.

<u>Author response #4</u>: The descriptions about the cut-off value have been revised in the Discussion section (Page 15-16) according to the reviewer's suggestion.

Reviewer point #5: The sample size in this study needs to be evaluated if is adequate to introduce a sensitive assessment tool that can be used as a key instrument in early diagnosis and detecting of swallowing impairment among older adults.

Author response #5: The power analysis of the sample size has been revised by evaluating whether the T-SSQ was a sensitive assessment tool for using as a key instrument in early diagnosis and detecting swallowing impairment among older adults. The revisions have been made in the Materials and Methods section (Power analysis subsection, Page 9)

Reviewer No. 2:

<u>Reviewer point #1</u>: Control group should have been included.

<u>Author response #1</u>: Our pilot study did not include patients who were diagnosed with dysphagia by physicians. Therefore, a positive control group was not present in this study. This was because we wanted to develop a screening tool for swallowing ability impairment rather than a tool for dysphagia diagnosis. This limitation has been added in the Discussion section (Page 17).

Reviewer point #2: Newly developed questionnaire should be validated. Statistics data should be furnished completely.

<u>Author response #2</u>: Descriptions about the validation of the newly developed questionnaire (T-SSQ) has been added in the Materials and Methods section (Phase I subsection). The statistical analysis has also been revised.

<u>Reviewer point #3</u>: Relevant figures with legends to be provided. Copy of questionnaire should be given.

<u>Author response #3</u>: The relevant figures with legends have been provided in the manuscript file. A copy of the questionnaire (in Thai, and English translation) has been provided as a supplementary file.

Additional responses to the comments in the attached Pdf files:

Materials and Methods section

The references of the Thai-version of the Mini-Nutritional Assessment (MNA) has been revised.

- The references for the tongue pressure measurement and the Thai-version of Mini-Mental

State Evaluation (MMSE) have been added.

To evaluate the reliability of the T-SSQ in older adults, the inter-examiner reliability was

examined in 15 patients at the patients' first evaluation visit. Test-retest reliability was

evaluated by reinterviewing these patients one week later. The descriptions have been

revised in the Swallowing ability assessment subsection (Page 8).

Results section

- The results for the descriptive statistics have been demonstrated in the Result section and

Tables.

- The statistical tests have been added as a footnote of Table 1.

Discussion section

- The patients who were unable to perform a tongue pressure test due to severely declined

functional or intellectual conditions were excluded. This exclusion criterion has been

included in the Materials and Methods section (Page 5).

- The study limitations have been added according to the reviewers' suggestions.

Sincerely yours

Orapin Komin

Corresponding author